

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	:	MDL No. 2804
OPIATE LITIGATION	:	
	:	Case No. 17-md-2804
This document relates to:	:	
	:	Judge Dan Aaron Polster
<i>Salmons v. Purdue Pharma L.P., et al.</i>	:	
MDL Case No. 1:18-op-45268;	:	
	:	
<i>Flanagan v. Purdue Pharma L.P., et al.</i>	:	
MDL Case No. 1:18-op-45405;	:	
	:	
<i>Doyle v. Purdue Pharma L.P., et al.</i>	:	
MDL Case No. 1:18-op-46327.	:	

**SUPPLEMENTAL DECLARATION OF DR. KANWALJEET ANAND
IN SUPPORT OF THE NAS GUARDIANS' REPLY
IN SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION**

I, Kanwaljeet S. Anand, hereby declare as follows:

1. I am a Pediatrician specialized in the care of critically ill newborns and children. I serve as a fully tenured Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine at Stanford University School of Medicine and as Director of the Pain/Stress Neurobiology Laboratory at Children's Hospital Research Institute.

2. I submit this Supplemental Declaration in support of the NAS Guardians' Reply in Support of Their Consolidated Motion for Class Certification and Appointment of Class Counsel.

3. My declaration dated January 28, 2020, states that "*Most clinicians diagnose NAS in children with modified Finnegan score of 8 or greater from two (2) consecutive assessments performed by a qualified healthcare practitioner with a minimum interval of 4 hours between the two consecutive NAS assessments*¹⁻⁴." The American Academy of Pediatrics (AAP) policy on "Neonatal Drug Withdrawal" does not give any guidance on threshold values of clinical scores required to make the diagnosis of Neonatal Abstinence Syndrome (NAS) or to initiate pharmacologic therapy⁵. **AAP Conclusion #6** states that: "*The optimal threshold score for the institution of pharmacologic therapy by using any of the published abstinence assessment instruments is unknown*"⁵.

Newborns with **no exposure** to prenatal opioids by maternal history, urine testing, and chemical analysis of the baby's meconium (first stool) were assessed using the Finnegan NAS score. Median Finnegan scores remained at 2 in the first 3 days of life, and 95th percentile scores

remained 7 or lower⁴. Therefore, a cut-off score of 8 or greater on the Modified Finnegan scale is uniformly accepted as a clinical criterion to assign the diagnosis of NAS. Babies may be irritable for some other reason (hunger, wet diaper) may occasionally show Finnegan NAS scores of 8-10. Therefore, it is recommended that **2 consecutive Finnegan NAS scores of 8 or greater or one Finnegan NAS score of 12 or greater** establishes a diagnosis of NAS. In a collaborative quality initiative across 199 hospitals, S.W. Patrick et al. found that standardized NAS scoring was associated with 3.3 days shorter hospital length of stay, even after adjusting for potential confounders⁶. In a systematic review of NAS assessment and management, Bagley et al. did not report any uniform criteria for the diagnosis of NAS⁷.

The Association of State & Territorial Health Officials (ASTHO)⁸ recommends that “*Screening for NAS should begin with a careful maternal history and physical examination and supplemented with toxicological testing as needed. Infants who are exposed to opioids should be observed in the hospital for 4-7 days and their symptoms assessed with the aid of an abstinence scoring tool ... there is no known optimal threshold score for starting pharmacological therapy for any of the published screening tools.*”

4. Based on the published medical literature, my knowledge, training and clinical experience, I declare that the children of Clients:

- (a) **Melissa Barnwell** [REDACTED]
- (b) **Jacqueline Ramirez** [REDACTED] and [REDACTED]
- (c) **Ashely Poe** [REDACTED]

do meet the class definition of clients with children suffering from NAS based on the criteria below:

[REDACTED]

References:

¹ Finnegan LP, Connaughton JF, Jr., Kron RE, Emich JP. Neonatal abstinence syndrome: assessment and management. *Addict Dis* 1975;2:141-58.

² Finnegan LP, Kron RE, Connaughton JF, Emich JP. Assessment and treatment of abstinence in the infant of the drug-dependent mother. *Int J Clin Pharmacol Biopharm* 1975;12:19-32.

³ Lifshitz M, Gavrilov V, Galil A, Landau D. A four year survey of neonatal narcotic withdrawal: evaluation and treatment. *Isr Med Assoc J* 2001;3:17-20.

⁴ Zimmermann-Baer U, Notzli U, Rentsch K, Bucher HU. Finnegan neonatal abstinence scoring system: normal values for first 3 days & weeks 5-6 in non-addicted infants. *Addiction* 2010;105:524-8.

⁵ Hudak ML, Tan RC, Committee On D, Committee On F, Newborn, American Academy

of P. Neonatal drug withdrawal. *Pediatrics* 2012;129:e540-60.

⁶ Patrick SW, et al. Improving Care for Neonatal Abstinence Syndrome. *Pediatrics* 2016;137.

⁷ Bagley SM, Wachman EM, Holland E, Brogly SB. Review of the assessment and management of neonatal abstinence syndrome. *Addict Sci Clin Pract* 2014;9:19.

⁸ Ramakrishnan M. Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care <https://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report/>. Arlington, VA: Association of State and Territorial Health Officials; 2014.

5. I have reviewed and relied on the attached peer-reviewed publications in forming my expert opinion in these actions. The attached two appendices with exhibits are for the Court's convenience. The complete list of documents that I relied on are set forth in my original declaration filed January 7, 2020, and further identified in my deposition taken on January 28, 2020. The peer-reviewed publications are reliable evidence in support of my opinions and would reasonably be relied upon by experts in Neonatal Abstinence Syndrome. Attached hereto are true and correct copies of the following two appendices with exhibits:

Appendix 1 (Filed Under Seal)

Exhibit A1: Barnwell medical records with Bates numbers [REDACTED] 000003-194.

Exhibit A2: Barnwell medical records with Bates numbers [REDACTED] 000001-235.

Exhibit A3: Barnwell medical records with Bates numbers [REDACTED] 000236-83, 288-337; Barnwell-000163-4; MelissaPBarnwellDanielAWatrousMDMedical001-3, 25.

Exhibit B: Ramirez medical records with Bates numbers [REDACTED] 000049-101, 171-248.

Exhibit C: Poe medical records.

Appendix 2 (Articles)

Exhibit A: Baldacchino A, Arbuckle K, Petrie DJ, et al. Neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis. *BMC Psychiatry*. 2014;14:104. doi:10.1186/1471-244X-14-104

Exhibit B: Baldacchino A, Arbuckle K, Petrie DJ, et al. Erratum: Neurobehavioral consequences of chronic intrauterine opioid exposure in infants and preschool children: a systematic review and meta-analysis. *BMC Psychiatry*. 2015;15:134. doi:10.1186/s12888-015-0438-5

- Exhibit C: Clemans-Cope L, Holla N, Lee HC, et al. Neonatal abstinence syndrome management in California birth hospitals: results of a statewide survey. *J Perinatol.* 2020;40:463-472. doi:10.1038/s41372-019-0568-6
- Exhibit D: Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *JAMA.* 2016;315(15):1624-1645. doi:10.1001/jama.2016-1464
- Exhibit E: Fill MA, Miller AM, Wilkinson RH, et al. Educational Disabilities Among Children Born With Neonatal Abstinence Syndrome. *Pediatrics.* 2018;142(3):e20180562. doi:10.1542/peds.2018-0562
- Exhibit F: Honein MA, Boyle C, Redfield RR. Public Health Surveillance of Prenatal Opioid Exposure in Mothers and Infants. *Pediatrics.* 2019;143(3):e20183801. doi:10.1542/peds.2018-3801
- Exhibit G: Jarlenski MP, Krans EE, Kim JY, et al. Five-Year Outcomes Among Medicaid-Enrolled Children With In Utero Opioid Exposure. *Health Affairs.* 2020;39(2):247-255. doi:10.1377/hlthaff.2019-00740
- Exhibit H: Logan BA, Brown MS, Hayes MJ. Neonatal Abstinence Syndrome: Treatment and Pediatric Outcomes. *Clin Obstet Gynecol.* 2013;56(1):186-92. doi:10.1097/GRF.0b013e31827feea4
- Exhibit I: Mazure CM, Fiellin DA. Women and opioids: something different is happening here. *Lancet.* 2018;392:9-11
- Exhibit J: Palumbo SA, Adamson KM, Krishnamurthy S, et al. Assessment of Probable Opioid Use Disorder Using Electronic Health Record Documentation. *JAMA Netw Open.* 2020;3(9):e2015909. doi:10.1001/jamanetworkopen.2020.15909
- Exhibit K: Patrick SW, Barfield WD, Poindexter BB, et al. Neonatal Opioid Withdrawal Syndrome. *Pediatrics.* 2020;146(5):e2020029074. doi:10.1542/peds.2020-029074
- Exhibit L: Rosenberg JM, Bilka BM, Wilson SM, et al. Opioid Therapy for Chronic Pain: Overview of the 2017 US Department of Veterans Affairs and US Department of Defense Clinical Practice Guideline. *Pain Med.* 2018;19(5):928–941. doi:10.1093/pm/pnx203
- Exhibit M: Rubenstein E, Young JC, Croen LA, et al. Brief Report: Maternal Opioid Prescription from Preconception Through Pregnancy and the Odds of Autism Spectrum Disorder and Autism Features in Children. *J Autism Dev Disord.* 2019;49(1):376–382. doi:10.1007/s10803-018-3721-8

- Exhibit N: Sirnes E, Griffiths ST, Auckland SM, et al. Functional MRI in prenatally opioid-exposed children during a working memory-selective attention task. *Neurotoxicol Teratol*. 2018;66:46-54. doi:10.1016/j.ntt.2018.01.010
- Exhibit O: Yeoh SL, Eastwood J, Wright IM, et al. Cognitive and Motor Outcomes of Children With Prenatal Opioid Exposure: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2019;2(7):e197025. doi:10.1001/jamanetworkopen.2019.7025
- Exhibit P: Kahn DJ, Richardson DK, Gray JE, et al. Variation Among Neonatal Intensive Care Units in Narcotic Administration. *Arch Pediatr Adolesc Med*. 1998;152:844-51
- Exhibit Q: Newville J, Maxwell J, Kitase Y, et al. Perinatal Opioid Exposure Primes the Peripheral Immune System Toward Hyperreactivity. *Front Pediatr*. 2020;8(272):1-12. doi:10.3389/fped.2020-00272
- Exhibit R: US Dept of Health and Human Services. Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. 2019, May. Available at <https://hhs.gov/ash/advisory-committees/pain/reports/index.html>
- Exhibit S: National Institute of Health, National Institute on Drug Abuse. Sex and gender differences in substance use. 2020, Jan. Available at <https://www.drugabuse.gov/publications/research-reports/>
- Exhibit T: Centers for Disease Control and Prevention. CDC Articles and Key Findings About Opioid Use During Pregnancy. 2019, Nov. Available at <https://cdc.gov/pregnancy/opioids/articles.html>
- Exhibit U: Centers for Disease Control and Prevention. Pregnancy and Opioid Pain Medications. Available at <https://cdc.gov/drugoverdose/prescribing/guideline.html>

I declare under penalty of perjury that the foregoing facts are true and correct.

Executed on November 11, 2020.



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